REMARKS

I. Introduction

In response to the Office Action dated October 1, 2003, claims 1 and 2 have been amended, and new claims 3-6 have been added. Claims 1-6 remain in the application. Reconsideration of the application, as amended, is requested.

II. Claim Amendments

Applicants' attorney has made amendments to the claims as indicated above. These amendments were made solely for the purpose of clarifying the language of the claims, and do not introduce new matter. Entry of these amendments is respectfully requested. Support for the amendments to the claims can be found in the application as originally filed as follows.

The amendment to claims 1 and 2 can be found in the specification at page 2, lines 17-19, and at page 3, lines 10-16.

New claims 3 and 5 are supported by the specification at page 3, lines 16-17.

New claims 4 and 6 are supported by the specification at page 5, line 20.

III. Non-Art Rejections

On page (2) of the Office Action, claims 1 and 2 were rejected under 35 U.S.C. §112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which Applicants regard as the invention. On page (3) of the Office Action, claims 1 and 2 were rejected under 35 U.S.C. §112, first paragraph, as failing to comply with the written description requirement. On page (4) of the Office Action, claims 1 and 2 were rejected under 35 U.S.C. §112, first paragraph, as failing to comply with the enablement requirement.

Each of these non-art rejections is based on the recitation of "functional equivalent thereof" following "Rev responsive element" in the claims. Although Applicants disagree with these rejections, as those skilled in the art are capable of readily identifying an element that serves as a functional equivalent of a Rev responsive element, Applicants have amended claims 1 and 2 to delete this phrase. Applicants recognize that the term "Rev responsive element" is understood to those skilled in the art to include elements capable of responding to Rev. Accordingly, the term "functional equivalent thereof" is redundant in this context.

IV. Prior Art Rejections

On page (6) of the Office Action, claim 1 was rejected under 35 U.S.C. §102(a) and §102(e) as being anticipated by Carrano et al., U.S. Patent No. 5,739,118 (Carrano). On page (7) of the Office Action, claims 1 and 2 were rejected under 35 U.S.C. §102(b) as being anticipated by Yu et al., "Journal of Virology, 1996" (Yu). Also on page (7) of the Office Action, claims 1 and 2 were rejected under 35 U.S.C. §102(a) as being anticipated by Kaul et al., "Virology, September 1998," (Kaul).

Independent claims 1 and 2 are generally directed to a nucleic acid construct comprising a promoter, a splice donor site, a gag/pol coding region, an RRE element, a splice acceptor site and a selectable marker, wherein the splice acceptor site is less efficient than the splice donor site. As discussed at page 2 of the specification, this strategic placement of splice control elements allows for expression of a downstream selectable marker gene in the basal state and of the upstream gag/pol genes only upon induction. This arrangement permits selection of cells that express gag and pol without expression of products of the gag and pol genes, which can be toxic. As discussed at page 3 of the specification, the use of less efficient splice sites allows for more efficient expression from unspliced transcripts by the Rev-RRE system.

The cited references do not teach nor suggest these various elements of Applicants' independent claims.

Carrano merely describes a method of introducing nucleic acid molecules into cells using nucleic acid molecules that are free of viral particles in conjunction with a genetic vaccine facilitator agent. However, Carrano lacks any discussion about suppressing gag/pol expression in the basal state and providing for inducible expression of gag/pol. Instead, Carrano teaches away from Applicants' invention because it describes using the constructs therein to achieve production of all viral structural proteins (gag, pol and env; see column 21, lines 15-30) for genetic immunization to protect against HIV infection. There is no teaching or suggestion to select a splice acceptor site that is of suboptimal efficiency. Because Carrano teaches use of a two innoculant vaccine to spatially segregate the structural genes, there is no motivation to modulate expression of gag/pol relative to expression of the selectable marker gene or to combine an efficient splice donor site with a less efficient splice acceptor site.

Neither Yu nor Kaul, taken alone or in combination with each other and/or Carrano, teaches all elements of Applicants independent claims 1 and 2. Neither Yu nor Kaul teach a construct that comprises a splice donor site upstream of the gag/pol coding region, nor that comprises a splice acceptor site positioned downstream of the RRE and upstream of the selectable marker gene. Moreover, neither Yu nor Kaul teaches or suggests selecting a splice acceptor site that is less efficient than the splice donor site, nor does either of these references teach or suggest the desirability of strategic placement of splice control elements to achieve expression of the selectable marker gene in the basal state while maintaining inducible expression of gag/pol.

Thus, Applicants submit that claims 1 and 2 are allowable over Carrano, Yu, and Kaul. Withdrawal of the rejections based on the prior art is respectfully requested.

V. Conclusion

In view of the above, it is submitted that this application is now in good order for allowance and such allowance is respectfully solicited. Should the Examiner believe minor matters still remain that can be resolved in a telephone interview, the Examiner is urged to call Applicants' undersigned attorney.

Respectfully submitted,

GATES & COOPER LLP
Attorneys for Applicant(s)

Howard Hughes Center
6701 Center Drive West, Suite 1050
Los Angeles, California 90045
(310) 641-8797

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By: _____
Name: Karen S. Canady
Reg. No.: 39,927

KSC/sjm/amb